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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/618,298	07/11/2003	Michael J. Yellin	C014CIPDIV1/2CON	6908

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EXAMINER	
GAMBEL, PHILLIP	
ART UNIT	PAPER NUMBER
1644	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/06/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/618,298	YELLIN ET AL.	
	Examiner	Art Unit	
	Phillip Gambel	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *1/8/07; 3/27/07*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-101* is/are pending in the application.

4a) Of the above claim(s) *14-20,24-31,37,57-71,77,83-85,88-91,94 and 96-101* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13, 21-23, 32-36, 38-56, 72-76, 78-82, 86-87, 92-93 and 95* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-101 are pending.

2. Applicant's election of the species "antibodies (Species A)" and the species "vasculitis (Species H)" in the Reply to Restriction Requirement, filed 1/8/07, is acknowledged.

Upon a review of the instant claims as they read on the elected species, the following is noted.

This application contains claims directed to the following patentably distinct species of the claimed Invention: wherein the "antibody / antibodies" is / are:

A) CD40-specific antibody / antibodies or
B) CD40L-specific antibody / antibodies.

These antibodies differ because the antigens that they bind are distinct because their structures and modes of action are different, which require non-coextensive searches. It is further noted that these antigens (CD40 and CD40L) do not comprise a common structure essential to a common utility. Therefore, they are patentably distinct.

Applicant is required under 35 U.S.C.121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic, for example.

3. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 of the other invention.

4. During a telephone conversation with James Haley on 03/27/2007, a provisional election was made to prosecute the *species of CD40L-specific antibodies* in addition to the species indicated above.

Affirmation of this election must be made by applicant in responding to this Office action.

Claims 1-13, 21-23, 32-36, 38-56, 72-76, 78-82, 86-87, 92-93 and 95 read on the elected invention.

The claims are being read in terms of the elected species, that is, anti-CD40L antibodies as the agent in the treatment of vasculitis.

In addition for the reasons below, the claimed therapeutic targets have been extended to the treatment of rheumatoid arthritis and systemic lupus erythematosus (SLE) in addition to treating vasculitis.

Claims 14-20, 24-31, 37, 57-71, 77, 83-85, 88-91, 94 and 96-101 have been withdrawn from further consideration by the Examiner, 37 C.F.R. 142(b), as being drawn to non-elected species.

5. The filing date of the instant claims is deemed to be the filing date of priority application USSN 08/567,391; filed 12/01/1995.

However, it is not clear that applicant has been timely in providing the proper claim for benefit of priority.
Applicant is invited to clarify whether they have been timely in claiming the benefit of priority in the instant application as-filed.
See Section 6.

6. If applicant desires to claim the benefit of a prior-filed application under 35 U.S.C. 120, a specific reference to the prior-filed application in compliance with 37 CFR 1.78(a) must be included in the first sentence(s) of the specification following the title or in an application data sheet. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications.

If the instant application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

In addition to verifying that the claim for benefit of priority was timely, applicant is required to update the first line of the specification to recite the appropriate priority documents, status and relationship.

7. The Abstract of the Disclosure is objected to because it does not adequately describe the claimed invention. Correction is required. See MPEP 608.01(b).

8. The application is required to be reviewed and all spelling, TRADEMARKS, and like errors corrected.

Trademarks should be capitalized or accompanied by the ® or ™ symbol wherever they appear and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the trademarks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

9. Claims 6 and 43 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 6 and 43 are indefinite in the recitation of "and a portion thereof" because it is not clear which portion is being referred to and the metes and bounds are not defined.

Applicant is invited to amend the claims to clearly define that the portions are antigen-binding fragments, provided there is written support in the specification as filed.

Applicant is reminded that the amendment must point to a basis in the specification so as not to add any new matter. See MPEP 714.02 and 2163.06

10. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 6, 11-12, 43 and 48-49 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention

A) Claims 6, 11-12, 43 and 48-49:
"a portion thereof" and "a complementarity determining region (CDR)".

The instant claims recite in various forms an antibody or antigen-binding portion thereof comprising "a portion thereof of an antibody" or "a CDR region"

The instant claims recite in some form "an antibody in which fewer than all CDRs or an entire variable region" are defined".

The breadth of the instant claims encompass antibodies or antigen-binding fragments thereof in which fewer than all of the six (6) CDRs found in the heavy plus light chain pair that forms the binding region of a referenced antibody are defined.

The state of the art has recognized that all three (3) CDRs of the heavy chain variable region and all three (3) CDRs of the light chain variable region were important for determining the ability of the antibody to bind antigen. For example, Bendig (Methods: A Companion to Methods in Enzymology 8:83-93, 1995) reviews that the general strategy for "humanizing" antibodies involves the substitution of all six (6) CDRs from a rodent antibody that binds an antigen of interest, and that all six (6) CDRs are involved in antigen binding (see entire document, but especially Figures 1-3).

While the instant antibodies are drawn to or encompass the elected species of binding CD40L, including the 5c8 antibody,, the same considerations apply to the genus of human antibodies defined only based upon "a portion" or "a CDR" of antibody.

Thus, the state of the art recognized that it would be highly unpredictable that an antibody comprising less than all six (6) CDRs from an antibody with a desired specificity would bind the same antigen. Thus the minimal structure which provides the function of CD40 binding appears to include six (6) CDRs (three (3) in the heavy chain variable region and three (3) in the light chain variable region) from the same antibody.

In addition, the skilled artisan recognized that single CDRs with the same amino acid sequence could be found in antibodies with diverse specificities. In particular, antibodies, which have not yet undergone affinity maturation may still utilize germline heavy and light chain sequences. Between antibodies utilizing the same germline heavy or light chain gene the skilled artisan would expect to find that one or more of the heavy and/or light chain CDRs were the same as that of an antibody with a different specificity, particularly CDRs 1 and 2 which are germline encoded completely in the variable region. However, the same CDR may also occur in antibodies having somatic mutations that bind different antigens.

The specification as filed provides no or an insufficient number of working examples showing that fewer than all six (6) CDRs are required for binding to CD40L. Neither does the specification appear to provide sufficient guidance as to which subsets of CDRs could be used in an antibody comprising less than all six (6) CDRs from an antibody having CD40L binding specificity and still maintain human CD40L binding. Without sufficient guidance, it would require undue experimentation of the skilled artisan to make antibodies or antigen-binding fragments thereof which could bind CD40L and be used in methods of inhibiting CD40L:CD40 interactions that comprised fewer than all six (6) CDRs from a parental antibody that bound CD40L.

Alternatively, applicant is invited to limit claims to include at least one entire variable region together with defining the CD40L antigen specificity.

Reasonable correlation must exist between the scope of the claims and scope of enablement set forth. Given the recognized unpredictable nature of making antibodies with a desired specificity having only "a potion" or "a CDR" of anti-CD40L antibody or less that all six (6) CDRs from a reference antibody and the lack of sufficient guidance provided in the specification; the experimentation left to those skilled in the art, is unnecessarily, and improperly, extensive and undue.

B) Claims: 21-23, 35—36, 51-53, 75-76:
5c8 antibody produced by the hybridoma having ATCC Accession No. 10916.

It is apparent that the 5c8 antibody is required to practice the claimed invention. As a required element, it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it is not so obtainable or available, the enablement requirements of 35 USC 112, first paragraph, may be satisfied by a deposit of the cell line / hybridoma which produces this antibody. See 37 CFR 1.801-1.809.

In addition to the conditions under the Budapest Treaty, applicant is required to satisfy that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent in U.S. patent applications.

Amendment of the specification to recite the date of deposit and the complete name and address of the depository is required. As an additional means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

Given the availability of the 5C8 antibody produced by the hybridoma designated as ATCC as evidenced by U.S. Patent No. 5,474,771 as well as U.S. Patent No. 6,592,868;
the requirements for the deposit of biological materials under 35 USC 112, first paragraph, for the 5C8 antibody produced by the hybridoma having ATCC Accession No. 10916 have been satisfied.

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless --

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

14. For examination purposes, vasculitis (the elected species) broadly refers to inflammation of a vessel.

See The Merck Manual of Diagnosis and Therapy, Sixteenth Edition, edited by Berkow et al., Merck Research Laboratories, Rahway, NJ, 1992; see pages 1315-1316.

Given the disclosure in The Merck Manual that vasculitis is central to the pathophysiology of rheumatic diseases and systemic lupus erythematosus (SLE),

the species election has been extend to include both rheumatoid arthritis and SLE, as treating either rheumatoid arthritis or SLE is deemed to be anticipatory to treating vasculitis in the interest of compact prosecution.

Further, given the number of copending applications by the inventorship, applicant is invited to clarify which therapeutic endpoints reads on the elected species of inhibiting vasculitis, such as those therapeutic endpoints that would anticipate or render obvious treating vasculitis.

For example, applicant is invited to clarify whether inhibiting vasculitis reads on inhibiting other inflammatory conditions, such as those claimed, including transplant rejection, ischemia and reperfusion or particular autoimmune conditions.

Therefore, issues of double patenting are held in abeyance until applicant clarifies the scope of the instant elected invention and how it reads on U.S. Patent No.copending applications and claimed limitations *except for the treatment of rheumatoid arthritis and SLE, given the prior art rejections set forth herein*.

15. For examination purposes, it is noted that CD40 ligand has been known as CD40L, 5c8, gp39 and CD154.

16. Claims 1-13, 21-23, 32-36, 38-46, 48-55, 72-76, 78-82, 86-87, 92-93 and 95 are rejected under 35 U.S.C. § 102(e) as being anticipated by Lederman et al. (U.S. Patent No. 6,592,868) (see entire document, including Claims) and as evidenced The Merck Manual of Diagnosis and Therapy, Sixteenth Edition, (edited by Berkow et al., Merck Research Laboratories, Rahway, NJ, 1992; see pages 1315-1316), which notes that it was known by the ordinary artisan that vasculitis was central to the pathophysiology of rheumatic diseases and systemic lupus erythematosus (SLE) to the ordinary artisan at the time the invention was made.

Lederman et al. teaches methods of inhibiting activation via 5c8 (i.e., CD40L) with 5c8-specific antibodies (i.e., CD40L-specific antibodies) (e.g., see column 10, paragraph 10 – column 12), including the use of monoclonal, chimeric and humanized antibodies and antigen-binding fragments, including the particular 5c8 antibody of the instant invention (e.g., see columns 6-8) in the treatment of various immune responses, including rheumatoid arthritis and SLE (e.g., see columns 10-11, particularly column 11, paragraph 5 and Claims) in various dosages and modes of administration to achieve effective amounts.

While it is noted that the prior art Lederman et al. does not teach treating vasculitis per se, given the disclosure in The Merck Manual that vasculitis is central to the pathophysiology of rheumatic diseases and systemic lupus erythematosus (SLE), the prior art teachings of treating rheumatoid arthritis and SLE is deemed to be anticipatory of the claimed elected therapeutic endpoint of treating vasculitis.

Although the reference is silent about treating vasculitis per se,
it does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure. See Bristol-Myers Squibb Company v. Ben Venue Laboratories 58 USPQ2d 1508 (CAFC 2001). "{i}t is a general rule that merely discovering and claiming a new benefit of an old process cannot render the process again patentable". In re Woodruff, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990). The mechanism of action does not have a bearing on the patentability of the invention if the invention was already known or obvious. Mere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention. In re Wiseman, 201 USPQ 658 (CCPA 1979). Granting a patent on the discovery of an unknown but inherent function would remove from the public that which is in the public domain by virtue of its inclusion in, or obviousness from, the prior art. In re Baxter Travenol Labs, 21 USPQ2d 1281 (Fed. Cir. 1991). See M.P.E.P. 2145.

Also, it is noted that products of identical chemical composition can not have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01.

Therefore, the administration of the prior art 5c8-specific antibodies including the 5c8 antibody itself would have had the inherent properties of meeting the claimed functional characteristics and attributes of the claimed methods (e.g., inhibiting cell activation, inhibiting CD40L:CD40 binding).

Further, with respect to the claimed screening procedures or product-by-process limitations within the claimed methods;
it is noted that the patentability of a product does not depend on its method of production. In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985). Also, see MPEP 2113.

On this record, it is reasonable to conclude that the same patient is being administered the same active agent by the same mode of administration in the same amount in both the instant claims and the prior art reference. The fact that applicant may have discovered yet another beneficial effect from the method set forth in the prior art does not mean that they are entitled to receive a patent on that method.

Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed limitations would be inherent properties of the referenced methods to treat rheumatoid arthritis or SLE with inhibitory 5c8-specific antibodies.

Where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may be an inherent characteristic of the prior art, it has the authority to require the applicant to prove that the subject matter shown in the prior art does not possess the characteristics relied on. In re Schreiber, 44 USPQ2d 1429 (Fed. Cir. 1997).

Also, see Ex parte Novitski 26 USPQ 1389 (BPAI 1993); Mehl/Biophile International Corp. V. Milgraum, 52 USPQ2d 1303 (Fed. Cir. 1999); Atlas Powder Co. V. IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999); Bristol-Myers Squibb Company v. Ben Venue Laboratories, 58 USPQ2d 1508 (CAFC 2001).

17. Claims 1-13, 21-23, 32-36, 38-56, 72-76, 78-82, 86-87, 92-93 and 95 are rejected under 35 U.S.C. § 102(e) as being anticipated by Black et al. (U.S. Patent No. 6,001,358) (see entire document).

Black et al. teaches methods of inhibiting a number of conditions (see columns 32-34), including rheumatoid arthritis, SLE as well as vasculitis (see column 33, lines 1, 14, 18, 29, 30, 57, 58, 64) with CD40L-specific antibodies (e.g. gp39-specific and 5C8-specific antibodies), including the use of monoclonal, chimeric, humanized and primatized antibodies and antigen-binding fragments thereof (columns 13-22) in conventional methods including various dosages and modes of administration to meet the needs of the patient and the nature of the disease or condition (columns 34-38).

While it is noted that the prior art Black et al. does not teach treating rheumatoid arthritis and SLE also involves vasculitis per se,
given the disclosure in The Merck Manual that vasculitis is central to the pathophysiology of rheumatic diseases and systemic lupus erythematosus (SLE),
the prior art teachings of treating rheumatoid arthritis and SLE is deemed to be anticipatory of the claimed elected therapeutic endpoint of treating vasculitis.

Therefore, the administration of the prior art 5c8-specific antibodies including the 5c8 antibody itself would have had the inherent properties of meeting the claimed functional characteristics and attributes of the claimed methods (e.g., inhibiting cell activation, inhibiting CD40L:CD40 binding).

Further, with respect to the claimed screening procedures or product-by-process limitations within the claimed methods;
it is noted that the patentability of a product does not depend on its method of production. In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985). Also, see MPEP 2113.

On this record, it is reasonable to conclude that the same patient is being administered the same active agent by the same mode of administration in the same amount in both the instant claims and the prior art reference. The fact that applicant may have discovered yet another beneficial effect from the method set forth in the prior art does not mean that they are entitled to receive a patent on that method.

Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed limitations would be inherent properties of the referenced methods to treat rheumatoid arthritis or SLE with inhibitory 5c8-specific antibodies.

Where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may be an inherent characteristic of the prior art, it has the authority to require the applicant to prove that the subject matter shown in the prior art does not possess the characteristics relied on. In re Schreiber, 44 USPQ2d 1429 (Fed. Cir. 1997).

Also, see Ex parte Novitski 26 USPQ 1389 (BPAI 1993); Mehl/Biophile International Corp. V. Milgraum, 52 USPQ2d 1303 (Fed. Cir. 1999); Atlas Powder Co. V. IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999); Bristol-Myers Squibb Company v. Ben Venue Laboratories 58 USPQ2d 1508 (CAFC 2001).

18. The non-statutory double patenting rejection, whether of the obvious-type or non-obvious-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); In re Van Ornam, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and In re Goodman, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321 (b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78 (d).

Effective January 1, 1994, a registered attorney or agent of record may sign a Terminal Disclaimer. A Terminal Disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

19. Claims 1-13, 21-23, 32-36, 38-56, 72-76, 78-82, 86-87, 92-93 and 95 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over

claims 1-18 of U.S. Patent No. 6,592,868 (Lederman et al.)

and as evidenced The Merck Manual of Diagnosis and Therapy, Sixteenth Edition, (edited by Berkow et al., Merck Research Laboratories, Rahway, NJ, 1992; see pages 1315-1316), which notes that it was known by the ordinary artisan that vasculitis was central to the pathophysiology of rheumatic diseases and systemic lupus erythematosus (SLE) to the ordinary artisan at the time the invention was made

for the reasons set forth above in the rejection under 35 USC 102(e).

Although the claims are not exactly the same, the instant and copending claims are drawn to the same or nearly the same antagonistic anti-CD40L antibodies to treat certain conditions involving vasculitis.

For the reasons addressed above, the patented methods of treating rheumatoid arthritis or SLE with CD40L-specific antibodies, including the 5c8 specificity, anticipates or renders obvious the instant claims.

20. No claim is allowed.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

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